

REMARKS

Applicants preliminarily note that they have filed three Information Disclosure Statements (filed on March 24, 2008, May 28, 2008, and June 5, 2008 respectively) that have not been considered by the Examiner to date. Applicants respectfully request their consideration.

Specification

The abstract of the disclosure stands objected to regarding the invention description. Applicants have amended the abstract for clarity, thereby obviated this objection.

Double Patenting

Claims 26 and 33 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 41, 154, 158, 164, and 166 of U.S. Patent No. 7,000,953. Applicants acknowledge the present double patenting rejection, and will consider filing a terminal disclaimer in the event that the claims become otherwise allowable.

Claim Rejections – 35 U.S.C. §112

Claims 26-33 stand rejected under 35 U.S.C. §112, first paragraph regarding the written description. Applicants respectfully disagree with the rejection and assert that claims 26-33 are supported by the specification.

The Office Action states that “the disclosure does not describe ‘placing an *epithelial delaminator* and moving the epithelial delaminator member to apply a mechanical force *beneath the epithelium* with a force ... *to lift the epithelium in a continuous layer but not to cut the stroma.*” Office Action, p. 3 (emphasis in original).

With respect to placing an epithelial delaminator, Applicants note that support for this can be found in at least Figs. 1-9 and paragraph 0039 of the specification, which states in part:

"The epithelial separator device 12 includes a separator 14, shown here in a first position located away from the eye 10. The separator 14 includes a device that can scrape the epithelium from the cornea such as a plate, a wire or a knife with a dull edge."

With respect to applying a mechanical force beneath the epithelium, Applicants note that support for this can be found in at least paragraph 0039 of the specification, which states in part: "[t]he separator 14 removes an epithelium layer 16 located above a corneal surface 18 of the eye 10."

With respect to a force to lift the epithelium in a continuous layer but not to cut the stroma, Applicants note that support for this can be found in at least the following portions of the specification:

"As the separator 14 travels to contact the eye 10, the corneal surface 18 is flattened." Applicants' Specification, para. 0042.

"The travel of the separator 14 is controlled to produce an epithelial disk 34 hinged at an edge 36 of the epithelial disk 34." Applicants' Specification, para. 0044.

"Since a typical thickness of an epithelial disk 36 includes about 50 microns, to preserve an epithelial disk 36, a separated epithelial disk is rolled onto the drum 42." Applicants' Specification, para. 0048.

"The separator 14 preferably pushes the bottom two to three layers of epithelial cells 1902 which probably contain a majority of the shear strength of the epithelial layer 16." Applicants' Specification, para. 0052.

"The separator 14 is not sharp enough to excise corneal tissue during operation of the epithelial separator device 12." Applicants' Specification, para. 0039.

"The separator 14 separates the epithelium layer 16 without cutting the cornea." Applicants' Specification, para. 0043.

The Office Action also states that "the disclosure does not describe 'a step of forming an epithelial flap and a step of peeling the epithelial flap to expose the stroma.'" Office Action, p. 3.

With respect to forming an epithelial flap, Applicants note that support for this can be found in at least Figs. 7-10 and paragraph 0044 of the specification, which states in part: "[i]n one embodiment, the travel of the separator 14 is controlled to produce an epithelial disk 34 hinged at an edge 36 of the epithelial disk."

With respect to peeling the epithelial flap to expose the stroma, Applicants note that support for this can be found in at least Figs. 7-10 and paragraph 0039 of the specification, which states in part "[t]he separator 14 removes an epithelial layer 16 located above the corneal surface 18 of the eye 10;" paragraph 0043 of the specification, which states in part "[a]s separator 14 travels along the cornea 10, the epithelium layer 16 is separated from the cornea;" and paragraph 0045 of the specification, which states in part "after the epithelial separator 12 is removed, a deepithelialized area 38 is exposed that corresponds to a shape and size of the area that the separator 14 contacted during travel."

The Office Actions states "the disclosure does not describe 'the step of reshaping the stroma and the step of applying a laser beam to the stroma.'" Office Action, p. 3.

Applicants note that support for this can be found in at least paragraph 0046 of the specification, which states in part "[t]he laser ablation forms an irradiated area 40 of the eye 10;" and paragraph 0038 of the specification, which states in part "[a] laser is used to help correct imperfections in the cornea."

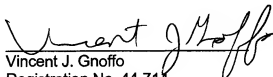
The Office Action states "the disclosure does not describe 'the step wherein the lifted epithelium contains substantially no corneal tissue.'" Office Action, p. 3.

Applicants note that support for this can be found in at least paragraph 0039 of the specification, which states in part "[t]he separator 14 is not sharp enough to excise corneal tissue during operation of the epithelial separator device 12," and paragraph 0043 of the specification, which states in part "[t]he separator 14 separates the epithelium layer 16 without cutting the cornea 18."

Because claims 26-33 are supported by the specification, Applicants respectfully request that the rejections to these claim be withdrawn.

Applicants respectfully request entry of this Amendment and allowance of this application. The Examiner is invited to contact the undersigned attorney for the Applicants via telephone if such communication would expedite this application.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Vincent J. Gnoffo", written over a horizontal line.

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